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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/067,638 04/28/98 COWSERT

L ISIS-2960

EXAMINER

HM12/0509

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ART UNIT

PAPER NUMBER

1631

DATE MAILED:

05/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/067,638

Applicant(s)

Cowsert et al.

Examiner
Ardin Marschel

Group Art Unit
1631



☒ Responsive to communication(s) filed on Jan 28, 2000

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 47-58 is/are pending in the application

~~Of the above, claim(s) 1-46 have been canceled.~~ ~~is/are withdrawn from consideration~~

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 47-58 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

The request, filed 1/28/00, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/067,638 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' arguments; filed 1/28/00, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 47-58 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In newly submitted claim 47, for example, three devices are listed as the first, second, and third devices. Each of these devices are specifically characterized therein. This specific citation of three devices with the characterizations as claimed has not been found as filed and is therefore NEW MATTER. For example, in the citations, filed 1/28/00, in support of these new

claims that are pointed to by applicants there is no mention of three separate devices. Secondly, the characterizations particularly of the first-third devices has not been found. It is acknowledged that the second device which automatically synthesizes real oligonucleotides is described in the specification but not as a separate device per se. The first device preparation of a virtual library as a separate device has not been found as filed, particularly a device which starts from a selected target nucleic acid sequence and prepares a library from such a target. It is noted that devices such as the third device are described in the instant specification which perform hybridization or immunoassay type assays but not a generic device that generically identifies a broadly generic "property" as now claimed in claim 47. Thus, this claim contains NEW MATTER as does claim 58 which goes even further in citing a fourth device. In claim 48 the preparing of a virtual library is inclusive as given of robotically preparing a virtual library. This robotic virtual library preparation is NEW MATTER in that it also has not been found as filed. The elimination of members from a virtual library as given in claim 52 has not been found as filed, nor the reduction of members via uniform distribution as given in instant claim 53. The generic chemical modifications, whether electronically applied or not, of claims 54 and 55 have not been found as filed. The NEW MATTER described above is also present

in claims that are directly or indirectly dependent from the above discussed claims via their dependence.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 47, 48, 50, and 52-58 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Gilbert (EPO 0,514,927).

In the abstract Gilbert describes an automated sequencer which comprises a oligomer synthesizer, an array, a detector, and a central computer which defines predicts oligomers. The synthesizer synthesizes them and they are utilized in a detector for sequencing by the property of hybridization. These are the three devices as also claimed in instant claim 47, for example. These devices are also depicted in the reference in Figure 1. On page 3, lines 17-22, these devices work to predict oligomers for each next round of synthesis and detection. The oligomers are predicted based on a target sequence that is being determined

during the overall sequencing process or, alternatively, from various starting sequences as summarized on page 17, lines 48-56. These genomic etc. starting sequences in said page 17 description anticipate the limitations of instant claims 56 and 57. The prediction of each round of oligomers occurs via a constructed nucleic acid sequence as disclosed in the sentence that bridges pages 3 and 4 of the reference. A more detailed description of these elements and steps is given on page 5, line 13, through page 17, line 5, with further refinements thereafter. The robotic or automatic computer control of hybridization in the reference is given on page 14, line 4, through page 15, line 55, as also required in instant claim 48. The reduction of oligomers of the virtual design library for probe selection via a set criteria is given on page 18, lines 6-22, wherein hairpin formation ability removes a potential probe from the set or, alternatively, removal of duplicates is a criteria as also required in instant claim 52. The walking sequence generation method of page 18, lines 17-22, also ensures a uniform distribution of probes across a target as also required in instant claim 53. Chemical modifications as required in instant claims 54 and 55 are also given as part of various modifications utilized in oligomer synthesis, optionally with labeling, as given in the reference on page 13, lines 17-54, which includes electronically controlled robotic practice. Lastly,

hybridization is either a biological, chemical, or physical property that is assayed via the utilization of various membrane bound oligomers in the multiple rounds of sequencing as noted in the reference in the above citations which anticipates instant claim 58.

Claims 47, 48, 50, and 54-57 are rejected under 35 U.S.C. § 102(b) and (e) as being clearly anticipated by Hubbell et al. (P/N 5,571,639).

In the abstract of Hubbell et al. the formation of arrays wherein a computer system selects probes and designs layouts is summarized. Figure 1 goes further in depicting devices with the functions of the devices as instantly claimed in that there is a item 100 computer which designs oligomer probes for chip design via utilizing a database which contains target sequences. Beyond this first computer there is a CPU containing synthesizer device and a device for analysis and another for detection. These are the basic limitations of instant claim 47. The automated chemical synthesis steps are deemed to anticipate instant claims 54 and 55. Array design, synthesis, and assay usage is specifically disclosed in column 3, line 51, through column 5, line 5, which also anticipates instant claim 1. Note also that in column 6, lines 1-17, describes target selection from various databases which is well known to inherently contain human sequences, genomic sequences, etc. as required in instant claims

56 and 57. The specific probe design for array preparation is disclosed by the tiling method, for example, in column 6, line 61, through column 9, line 21. Oligomer synthesis is then performed by computer control as given in column 9, line 22, through column 18, line 12. Detection assaying is performed by scanning devices as given in column 18, line 15, through column 19, line 26, as well as discussed hereinabove.

Patent Number 5,856,101 is cited on the enclosed PTO Form 892 as being cumulative to Patent Number 5,571,639 by Hubbell et al.

No claim is allowed.

Papers for this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 4, 2000

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER